

WSA 2003 Proposed Project

Project Name:	Influence of Smoking the EHCSS ACCORD® K3/K6 Puff Activated Lighter™ on Endothelium-Dependent Venoreactivity	
Brief Description of Project:	Assessment whether and to which extent endothelium-dependent venoreactivity is influenced by smoking conventional cigarettes, PREPs, or no-smoking and can be assessed non-invasively. A positive result will qualify the method for risk and harm reduction trials. Smokers of conventional cigarettes will be forced to switch to EHCSS ACCORD K3/K6 and to no smoking in a crossover design (Study duration 3 weeks/individual).	
Type of Deliverable(s):	<input checked="" type="checkbox"/> Assay <input checked="" type="checkbox"/> Knowledge <input type="checkbox"/> Product Development Guidance <input checked="" type="checkbox"/> Short Term <input checked="" type="checkbox"/> Product Evaluation <input type="checkbox"/> Long Term	
Reason for Doing this Work:	<input type="checkbox"/> Cancer <input checked="" type="checkbox"/> CVD <input type="checkbox"/> COPD <input type="checkbox"/> Repro <input type="checkbox"/> ETS <input type="checkbox"/> Determinants of Smoke Exposure <input type="checkbox"/> Product Design Guidance <input type="checkbox"/> PI Specific Projects <input type="checkbox"/> CE Specific Projects <input type="checkbox"/> Sensory Specific Projects <input type="checkbox"/> Scientific Affairs & Communication Specific Projects <input type="checkbox"/> WSA PMI Specific Projects (Neuchatel & Asia) <input type="checkbox"/> PMRL Specific Projects (Germany & Belgium)	
Program Area: (Check all areas that apply)		
Project Leader:	Martin Unverdorben	
Prioritization:	<input checked="" type="checkbox"/> Critical <input type="checkbox"/> Priority <input type="checkbox"/> Secondary <input type="checkbox"/> Low	
Milestones:		Target Date:
The timelines are subject to approval of EHCSS by the German Authorities. Final Protocol Venoreactivity Tests Lab Analysis Data Evaluation Draft Report Final Report Abstract Draft Manuscript		March 2003 Sept.03-May04 June 2004 July 2004 September 2004 October 2004 November 2004 December 2004
Internal Resource Allocation (WSA, PMRL, PMI) (Man Hours)		External Resource Allocation (other PMUSA, external vendors) (Man Hours)
WSA, PMUSA		Conduct of Study by Prof. Dr. W.Haefeli, University of Heidelberg

TO BE FILLED OUT BY WSA MANAGEMENT

- ☐ Approved as Written
☐ Approved with Modifications
☐ Not Approved
 Reason: _____

Signature of Coordinator (Date)

Signature of Project Leader's Functional Director (Date)